UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF RALPH ZIPPER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this reply in support of their motion to exclude certain opinions of Ralph Zipper, M.D.

INTRODUCTION

Defendants have filed a motion seeking to exclude the following opinions proffered by Dr. Zipper regarding Defendants' Prosima and Prolift devices:

- Alleged design defect opinions concerning mesh degradation, contraction, and extrusion that require biomaterials expertise that Dr. Zipper does not have;
- Alleged design defect opinions that are not supported by application of a reliable methodology;
- Alleged defective warnings contained in the Prosima and Prolift Instructions for Use ("IFU") that are outside of his expertise or that are not supported by a reliable methodology;
- "Safer" alternative products and procedures whose comparative safety and efficacy have not been quantified;
- Opinions about Ethicon's alleged knowledge, state of mind and bad acts; and
- Opinions regarding Ethicon's alleged fraud on the FDA.

Plaintiffs have largely failed to respond to Defendants' arguments regarding alternative procedures, his unreliable methodology of relying on the FDA's MAUDE database, and the vast majority of his reports that are mere historical commentary. By failing to respond to these arguments, Plaintiffs have conceded them, as this Court has repeatedly declined to make arguments for parties. *See, e.g., Ramsey v. Bos. Sci. Corp.*, 2016 WL 2622006, at *4 (S.D. W.Va. May 5, 2016) ("The plaintiff does not address the majority of BSC's arguments on this point, and I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing.")

Additionally, Plaintiffs concede that they will not elicit any testimony from Dr. Zipper regarding Defendants' knowledge, state of mind, or alleged bad acts. (Resp. in Opp'n ("Resp.') at 10 (D.E. 2190)). Plaintiffs spend the majority of their response attempting futilely to convince the Court that Dr. Zipper's opinions are gained through experience and are based on sound methodology. They are not. Dr. Zipper's "experience" is, by his own admission, gained through litigation. He further fails to apply his purported methodology to all mesh products that he uses or opines on. For all of these reasons, and consistent with the foregoing, the Court should limit Dr. Zipper's testimony.

I. Dr. Zipper's Opinions That The Prosima And Prolift Were Defectively Designed Are Unreliable.

As demonstrated in Defendants' Motion, Dr. Zipper is not qualified to offer opinions regarding alleged design defects of Prosima and Prolift, nor are any of his opinions with respect to design defects reliable. (Mem. In Supp. of Mot. to Exclude ("Mem. In Supp.") at 3-10 (D.E. 2072)). In response, Plaintiffs rely on a Pennsylvania state court case in which Dr. Zipper was not excluded to argue that the result should be the same here. (Resp. at 2). Simply because a Pennsylvania state court has found Dr. Zipper qualified to testify in that jurisdiction does not

mean that this Court must accept his conclusory statements and his unreliable methodology. Plaintiffs contend that Dr. Zipper is qualified to opine regarding the biomaterial properties of mesh, including degradation, because he has "performed thousands of transvaginal mesh procedures" and "explanted over 500 pieces of mesh." (Resp. at 4). This response essentially boils down to the contention that Dr. Zipper is an established urogynecologist with years of experience; therefore, the Court should find him qualified to testify as to biomaterial properties of mesh. This type of argument has failed to persuade this Court on previous occasions, *see, e.g.*, *Ramsey*, 2016 WL 2622006, at *5 ("The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products."), and it is no more persuasive now.

Plaintiffs additionally contend that Dr. Zipper has "worked with engineers to develop and commercialize devices for the treatment of urinary incontinence," (Resp. at 5), but offers no evidence that Dr. Zipper himself designs the products. He merely "visits the [materials] manufacturer," "examines the manufacturing process and the materials produced," and occasionally "reviews the *Material Data Safety Sheet*." (*Id.*). Not only does Dr. Zipper's work with engineers fail to qualify *him* to offer opinions based on those engineers' knowledge, skill, experience, or training (*see* Mem. In Supp. at 5), this Court has previously precluded a urogynecologist from testifying about product design where the urogynecologist lacked experience with the actual design of the product. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 581 (S.D. W. Va. 2014). It should do the same in this case.

More importantly, Plaintiffs wholly fail to address Defendants' contention that Dr. Zipper's methodology is unreliable. (*See* Mem. In Supp. at 7-8). Although Dr. Zipper has

vigorously campaigned against Defendants' polypropylene mesh products by criticizing their safety and the way in which they were approved by the FDA, when confronted with questions regarding his application of these criteria to a polypropylene mesh he uses today, called Alyte Y, Dr. Zipper admitted that he does not apply these criteria to Alyte Y. (*Id.*). Plaintiffs do not even bother trying to explain this discrepancy. His opinion does not "comport[s] with the dictates of good science" as required by *Daubert*, *see Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014) *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014), and is not the product of reliable principles and methods applied to the facts of this case. Dr. Zipper's opinions regarding design defect should be excluded. *See Stewart v. Bos. Sci. Corp.*, 2016 WL 2654080, at *11 (S.D. W. Va. May 9, 2016) (excluding Dr. Blaivas's opinion because he applied standards different than those he applies in his medical practice).

II. Dr. Zipper's Has Not Offered a Sufficient Basis for His Opinions That There Were Safer Alternative Products or Procedures.

Dr. Zipper opines that there were a number of other alternative products or techniques that were equally effective to treat pelvic organ prolapse than the Prolift, such as native tissue surgeries and a variety of other mesh products. (Mem. In Supp. at 10-13). Defendants have moved to exclude these opinions on two grounds. First, alternative surgeries are techniques, not products, and do not satisfy the Plaintiffs' burden of establishing a safer alternative *design*. Plaintiffs have failed to respond to this argument, and so these opinions should be excluded. (Resp. at 8).

Second, for Dr. Zipper to opine that traditional surgical procedures are safer alternatives to Ethicon's products presumes that all mesh products are unsafe. (Mem. In Supp. at 11). Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s

physician, not with a specific fault of" the device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999) (surgical alternative to pedicle screw could not be considered). Plaintiffs' response obliquely addresses "alternative designs using larger pore, lighter weight mesh (e.g., Ultrapro)," but given Dr. Zipper's underlying opinion that traditional, non-mesh procedures are all safer than mesh itself, he cannot reliably opine that "larger pore, lighter weight mesh" is a safer alternative design. (Resp. at 8).

Furthermore, Defendants argued that Dr. Zipper had failed to disclose testing that supported his opinion and failed to link his conclusions to the analysis that he performed with respect to any such testing. (Mem. In Supp. at 11-12). In their Response, Plaintiffs still provide no evidence that Dr. Zipper tested this theory, citing generically to "numerous publications and internal documents." (Resp. at 8). This is clearly insufficient to demonstrate the reliability of Dr. Zipper's opinions. *See, e.g.*, *Johnson v. Manitowoc Boom Trucks, Inc.*, 406 F. Supp. 2d 852, 860-62 (M.D. Tenn. 2005) (stating that "testing is important, especially in the context of a theory involving a proposed alternative design"); *see also Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 538 (7th Cir. 2000) (holding the lower court did not err in excluding expert testimony in large part because the expert had not tested his alternative design). His opinions regarding safer alternative design should be excluded.

III. Dr. Zipper Admittedly Became an Expert in Warnings Through Litigation, and He is Not Qualified to Offer Opinions Regarding The Adequacy Of The Prosima And Prolift IFUs.

Ethicon has moved to dismiss Dr. Zipper's opinions the IFUs that accompanied the Prosima and Prolift were defective and failed to provide adequate warnings and information to treating surgeons. (Mem. In Supp. at 13-14). In particular, Dr. Zipper has insufficient experience in preparing a medical device IFU and no training concerning FDA regulations

related to developing warnings or labeling. (*Id.* at 13). More critically, however, Dr. Zipper has essentially testified that he has become an expert in labeling and the FDA regulatory process through litigation. (*Id.*). Plaintiffs fail to respond to this argument in their Response. (Resp. at 8-9). This fact alone counsels against the admission of his testimony regarding warnings. *See Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998) ("Another significant fact weighing against admitting the testimony is where, as here, the expert developed his opinions expressly for the purposes of testifying.").

Instead, Plaintiffs simply rehash their generic arguments that Dr. Zipper is qualified to testify regarding warnings through his "design development endeavors and the consulting work he has provided to medical device manufacturers." (Resp. at 9). As demonstrated above, Dr. Zipper himself has not actually designed a pelvic medical device, and this argument is therefore unpersuasive as evidence of relevant experience. Tellingly, all Dr. Zipper can rely on is his "years of clinical experience, [his] knowledge, [his] training, [his] review of the peer-reviewed literature [and] non-peer-reviewed literature, [and his] consulting work which includes the reviewing of IFUs." (*Id.*) Dr. Zipper may have years of experience and consulting work, but this does not establish his familiarity with the *process* of developing product warnings, as was required by this Court in *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding plaintiff's expert, Dr. Bob Shull, on warnings and labels for medical devices: "Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process"). Dr. Zipper's opinions regarding warnings should be excluded.

IV. The Court Should Exclude Dr. Zipper's Opinions That Ethicon Misled or Committed Fraud on the FDA.

Defendants have moved to exclude Dr. Zipper's opinions that Ethicon submitted misleading information to the FDA in connection with its devices or was "deceitful" in its correspondence with the FDA. (Mem. In Supp. at 17-18). This Court has previously specifically precluded an expert from testifying that Ethicon deceived the FDA. *See Lewis v. Ethicon, Inc.*, Case No. 2:12-cv-4301, 2014 WL 186872, at *15 (S.D. W. Va. Jan. 15, 2014). In their Response, Plaintiffs confusingly state that they "recognize the Court's prior rulings on the admission of FDA testimony as it relates to the FDA and will adhere to any future rulings with respect thereto in this case." (Resp. at 10). Ethicon interprets this non-specific statement to be a concession by Plaintiffs that they will not elicit any testimony from Dr. Zipper to the effect that Ethicon was deceitful in its communications with the FDA or otherwise committed fraud on that agency. It is difficult to parse exactly what Plaintiffs "recognize," however, as they also insist that they "must be able to" respond to any proof by Ethicon regarding the FDA and Ethicon's 510(k) submissions with opinion testimony from Dr. Zipper that Ethicon was, in fact, "deceitful." Plaintiffs cannot have it both ways: they cannot both adhere to the Court's prior rulings barring testimony of deceitfulness and proffer evidence regarding deceitfulness. The Court should bar this testimony in its entirety, consistent with its prior opinions.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Zipper's testimony consistent with the foregoing.

Respectfully submitted,

ETHICON, INC. AND
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CERTIFICATE OF SERVICE

I certify that on May 16, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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